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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/566,109

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EXAMINER

STUART, COLIN W

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/566,109	<b>Applicant(s)</b> MAKINSON ET AL.	
	<b>Examiner</b> COLIN STUART	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. This office action is in response to the amendments filed 6/22/09. As directed by the amendment, claims 1, 6, 8, and 10-12 have been amended and claims 13-14 cancelled. As such, claims 1-12 are pending in the instant application.

### ***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**3. Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenyon et al. (6,397,841) in view of Mulvaney et al. (2003/0070544).**

In regards to claim 1, Kenyon shows a humidified gases delivery apparatus which includes a housing 32, a pressurized gasses supply 12 within the housing, a pressurized gases outlet 22 in the housing in fluid connection with the pressurized gases supply and adapted to make fluid connection with an inlet of a humidifier in order to provide gases flow to a humidifier 26 (Fig. 1). Kenyon is silent as to providing a removable filter in the inlet of the humidifier to filter the gases entering the humidifier and protect the gases supply and housing from contamination. However, Mulvaney teaches a humidifier apparatus which includes a removable filter (44 see para 0025 In. 1-7 Mulvaney). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Kenyon device to include a removable filter as taught by Mulvaney in order to remove "contaminants such as dust, pollen, mold spores, and the like" (Mulvaney para 0025 In. 12-13).

In regards to claim 2, the modified Kenyon's device includes a humidified gases return in said housing, adapted to make fluid connection with an outlet of a said humidifier in order to receive humidified gases from said humidifier, (connection outlet 24; Kenyon et al. Fig. 1) and a patient outlet in said housing, in fluid connection with said humidified gases return in order to receive humidified gases from said humidified gases return and provide humidified gases to said patient outlet, said patient outlet being in fluid connection with or adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient. (breathable gas outlet 14; Kenyon et al. Fig. 1).

**4. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenyon et al. (6,397,841) and Mulvaney et al. (2003/0070544) as applied to claims 1 or 2 above, and further in view of Mayer et al. (7,096,864).**

In regards to claim 3, the modified Kenyon's device teaches all the limitations as discussed above, but is silent as to explicitly disclosing that the humidifier is a heatable water chamber with the limitations as claimed. However, Mayer teaches a device for supplying respiratory gases which includes a humidifier as a heatable water chamber as claimed. (humidifying apparatus 2; Fig. 1 of Mayer et al.) Mayer et al. also teaches "introducing humidifying water into the liquid storage container 17" of the humidifying apparatus (col. 12 ln. 50; Fig. 1 of Mayer et al.) Mayer et al. also teaches that said apparatus includes, a chamber heating means connected to said housing as claimed. Mayer et al. discloses that the "water bath [of liquid in container 17] is preferably slightly

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heated by means of a heating device" (col. 3 In. 58 Mayer). The humidifying apparatus including the heating means, when substituted for the humidifier of modified Kenyon et al., is connected to the housing as claimed. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the humidifier of modified Kenyon et al. with the humidifying apparatus in view of Mayer et al., because Mayer et al. states that the humidifying apparatus is "coupled directly laterally to a CPAP-unit easily and without the need for expert assembly procedures" (col. 1 In. 64 Mayer).

In regards to claim 4, the modified Kenyon's device includes an apparatus according to claim 3 wherein said humidification chamber has a base (base body 16; Fig. 1 of Mayer et al.). In regards to the claimed said chamber is engagable with said humidifier engagement via a single motion, and said single motion of engagement urges the base of said humidification chamber adjacent and in contact with said chamber heating means, connecting the substituted humidifying apparatus of Mayer et al. for the humidifier of Kenyon et al. would only require a single motion of connecting the tubes (24 & 25 Kenyon) with the humidifying apparatus. Connecting the substituted humidifying apparatus with the rest of the device of Kenyon et al. also makes a first fluid connection between said pressurized gases outlet and said humidifier inlet, and makes a second fluid connection between said humidified gases return and said humidifier outlet, with said first and second fluid connections being made in the direction of said single motion as claimed.

**5. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kenyon et al. (6,397,841) and Mulvaney et al. (2003/0070544) as applied to claim 2 above, and further in view of Edirisuriya et al. (6,953,354).**

In regards to claim 5, the modified Kenyon's device teaches all the limitations as discussed above, but is silent as to the patient outlet including a connector for receiving a breathing hose **and** at least one auxiliary electrical connection plug or socket or pneumatic connection plug or port, for a simultaneous connection with connecting a breathing circuit having complementary electrical and pneumatic connectors. However, Edirisuriya teaches a patient outlet including a connector for making fluid connection and at least one auxiliary electrical connection plug or socket or pneumatic connection plug or port (618 Edirisuriya Fig. 35). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Kenyon's device to include the patient outlet including the at least one auxiliary connection as taught by Edirisuriya in order to allow the patient conduit to include an active heating element to prevent loss of heat and humidity due to condensation in the conduit.

**6. Claims 6 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickinson et al. (6,398,197) in view of Mulvaney et al. (2003/0070544).**

In regards to claim 6, Dickinson teaches a humidified gases delivery apparatus which includes a container 4 with a surrounding wall and top, and an open bottom (see Fig. 2 & 3), a heat conductive base 6 enclosing the open bottom of the container (see Fig. 3, a gases inlet 2 to the container, and an gases outlet 3 to the container (see Fig. 2

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& 3). Dickinson is silent as to providing a removable filter in the inlet of the humidifier to filter the gases entering the humidifier and protect the gases supply and housing from contamination. However, Mulvaney teaches a humidifier apparatus which includes a removable filter (44 see para 0025 ln. 1-7 Mulvaney). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Dickinson device to include a removable filter as taught by Mulvaney in order to remove "contaminants such as dust, pollen, mold spores, and the like" (Mulvaney para 0025 ln. 12-13).

In regards to claim 12, the modified Dickinson's device includes a cylindrical chamber (see Fig. 2 Kenyon) but is silent as to explicitly disclosing that the inlet and outlet ports are **both** a female port (note only inlet 2 Dickinson clearly shows female port). However, one of ordinary skill in the art at the time the invention was made would have found it obvious to choose the ports to be a female connection port (as opposed to a male connection port) as this is considered to be a matter of design choice. Furthermore one would expect the modified Dickinson's device to perform equally as well with the claimed both female ports. Note that the ports open out to the cylindrical surface adjacent the top of the cylinder wall.

**7. Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dickinson et al. (6,398,197) and Mulvaney et al. (2003/0070544) as applied to claim 6 above, and further in view of Hoffsrichter (DE 10,226,160) and Kenyon et al. (6,397,841).**

In regards to claim 7, the modified Dickinson device teaches all the limitations as discussed above, including a first elongate flow tube extending into the humidifier container from the inner periphery of the gases inlet (7 Fig. 2 of Dickinson). However, the modified Dickinson device is silent as to including a second elongate flow tube extending into said humidifier container from the inner periphery of said gases outlet. Hoffrichter teaches an air humidifier for a respirator which includes a tube extending into the humidification chamber from the inner periphery as claimed. (gauge-edge 18 of outlet pipe 9; Fig. 4 Hoffrichter) The two flow tubes taught by Hoffrichter are substantially parallel to each other, and substantially parallel to said base of said chamber. (See Fig. 4 Hoffrichter) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the gases outlet of the modified Dickinson's device to include a parallel tube extending into the humidification chamber in view of Hoffrichter, because Hoffrichter states that this allows "the air current mixes with the steam without resistance, yet prevents water from flowing back" (Abstract Hoffrichter). The now modified Dickinson's device is silent as to having said gases inlet and said gases outlet facing the same direction, a preferred insertion direction, and said preferred insertion direction is substantially parallel to the said base of said chamber, such that said humidifier chamber may make operable engagement with a heater base in a single motion, and fluid connections with said gases outlet and said gases inlet, being also made in said single motion. Kenyon teaches a humidification apparatus where the gases inlet and outlet are facing the same direction and parallel to the base. (See Fig. 3 Kenyon) The inlet and outlet tubes are also parallel to the single motion



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engagement direction which make fluid connections during engagement. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the modified device of Dickinson et al. to have the gases inlet and outlets configured in view of Kenyon, because Kenyon states that the engagement setup advantageously allows "the apparatus can be quickly and easily converted between including, or not including, a humidifier in the gas supply path" (col. 4 ln. 10).

In regards to claims 8 and 10, the modified Dickinson's device includes a filter means including a framework substantially supporting a filter material, shaped to fit the internal shape of the inlet and is locked in place by friction fit (see Mulvaney para 0025 and Figs. 2 & 4).

In regards to claim 9, the modified Dickinson's device includes a filter wherein the filter material is interposed between structural members of the framework (see Mulvaney Fig. 2).

In regards to claim 11, the modified Dickinson's device is silent as to the second flow tube including an air bleed orifice. However, Kenyon teaches a humidifier device which includes an air bleed orifice (64 Fig. 6 Kenyon) on a flow tube. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Dickinson's device's second flow tube to include an air bleed orifice as taught by Kenyon in order to provide a port in which sensors/transducers can monitor the activity of the device (see Kenyon col. 4 ln. 44-50).

**8. Claims 1-4 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer et al. (WO 2004/026382) in view of Mulvaney (2003/0070544).**

In regards to claim 1, Kramer teaches a humidified gases delivery apparatus which includes a housing ("CPAP machine has a housing" (pg. 7 ln. 4)), a pressurized gases supply within said housing, ("CPAP machine has a housing containing a blower" (pg. 7 ln. 5)), a pressurized gases outlet in said housing in fluid connection with said pressurized gases supply and adapted to make fluid connection with an inlet of a humidifier in order to provide gases flow to a said humidifier, (outlet port 4; Fig. 1) but Kramer et al. is silent to including a filter means on or over said inlet of said humidifier to filter said gases entering said humidifier. However, Mulvaney teaches a humidifier apparatus which includes a removable filter (44 see para 0025 ln. 1-7 Mulvaney). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Kramer device to include a removable filter as taught by Mulvaney in order to remove "contaminants such as dust, pollen, mold spores, and the like" (Mulvaney para 0025 ln. 12-13).

In regards to claim 2, the modified Kramer's device also includes a humidified gases return in said housing, adapted to make fluid connection with an outlet of a said humidifier in order to receive humidified gases from said humidifier, (inlet port 7; Fig. 1 Kramer) and a patient outlet in said housing, in fluid connection with said humidified gases return in order to receive humidified gases from said humidified gases return and provide humidified gases to said patient outlet, said patient outlet being in fluid

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connection with or adapted to make fluid connection with a breathing conduit for delivery of humidified gases to a patient. ("outlet port 9 which is adapted to connect with a flexible conduit connector for delivery to a patient" (pg. 8 ln. 19); Fig. 1 Kramer)

In regards to claim 3, the modified Kramer's device also discloses a heatable water chamber, (2 Fig. 1 Kramer), and said apparatus includes, a chamber heating means connected to said housing (chamber heating means 58; Fig. 1 Kramer) and said housing includes a humidifier engagement locating a said humidifier adjacent said chamber heating means, said chamber heating means adapted to vaporize liquid water in said water chamber in order to provide water vapor to said gases flow passing through said water chamber. (receiving bay 47; Fig. 1 Kramer)

In regards to claim 4, the modified Kramer's device also discloses the humidification chamber has a base and said chamber is engagable with said humidifier engagement via a single motion, and said single motion of engagement urges the base of said humidification chamber adjacent and in contact with said chamber heating means and makes a first fluid connection between said pressurized gases outlet and said humidifier inlet, and makes a second fluid connection between said humidified gases return and said humidifier outlet, with said first and second fluid connections being made in the direction of said single motion. ("complete connection or disconnection of the water chamber from the CPAP system (including the breathing conduit) can be achieved with a single slide-on or slide-off motion respectively" (pg. 8 ln. 23) Kramer)

In regards to claim 6, Kramer shows a humidifier chamber for use with a gases humidification apparatus including: a container, with a surrounding wall and top, and an open bottom, ("the chamber ... is constructed from an open bottomed plastic container" (pg. 11 ln. 17)) a heat conductive base enclosing said open bottom of said container, ("container enclosed by a heat conductive base 24" (pg. 11 ln. 18); Fig. 4) a gases inlet to said container, (gases inlet 27; Fig. 4) a gases outlet to said container, (gases outlet 28; Fig. 4) but is silent to including a filter means on or over said inlet to said container to filter said gases to said container. However, Mulvaney teaches a humidifier apparatus which includes a removable filter (44 see para 0025 ln. 1-7 Mulvaney). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Kramer device to include a removable filter as taught by Mulvaney in order to remove "contaminants such as dust, pollen, mold spores, and the like" (Mulvaney para 0025 ln. 12-13).

In regards to claim 7, the modified Kramer's device also includes a first elongate flow tube extending into said humidifier container from the inner periphery of said gases inlet (inlet extension tube 30; Fig. 4 Kramer) and, a second elongate flow tube extending into said humidifier container from the inner periphery of said gases outlet, (outlet extension tube 31; Fig. 4 Kramer) said first and said second flow tubes being substantially parallel to each other, and substantially parallel to said base of said chamber, and said gases inlet and said gases outlet facing the same direction, (tubes are parallel to base and each other and face the same direction; see Fig. 4 Kramer) a preferred insertion direction, and said preferred insertion direction is substantially

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parallel to the said base of said chamber, such that said humidifier chamber may make operable engagement with a heater base in a single motion, and fluid connections with said gases outlet and said gases inlet, being also made in said single motion.

("complete connection or disconnection of the water chamber from the CPAP system (including the breathing conduit) can be achieved with a single slide-on or slide-off motion respectively" (pg. 8 ln. 23); see Fig. 1 for water chamber insertion into base of CPAP machine; Kramer)

### ***Response to Arguments***

9. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents are considered to be pertinent art: Dobson et al. (5,564,415), Rose et al. (5,231,979), and Moberg (6,718,974).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 3771

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